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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/952,741 11/25/97 HATADA

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BIRCH STEWART KOLASCH & BIRCH
P O BOX 747
FALLS CHURCH VA 22040-0747

EXAMINER

SLOBODYANSKY, E

ART UNIT	PAPER NUMBER
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1652

18

DATE MAILED:

05/24/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/952,741

Applicant(s)
Hatada et al.

Examiner
Elizabeth Slobodyansky

Group Art Unit
1652



☒ Responsive to communication(s) filed on Mar 10, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 2-7, 9, and 11-21 is/are pending in the application.

Of the above, claim(s) 9, 11, and 17-19 is/are withdrawn from consideration.

☒ Claim(s) 12 and 13 is/are allowed.

☒ Claim(s) 2-7, 14-16, 20, and 21 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1652

DETAILED ACTION

Continued Prosecution Application

The request filed on March 10, 2000 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/952,741 is acceptable and a CPA has been established. An action on the CPA follows.

The amendment file January 14, 2000 amending the specification to correct typographical errors, canceling claims 8 and 10, amending claim 3 and adding claims 20 and 21 has been entered.

Claims 2-7, 12-16, 20 and 21 are under consideration, claims 9, 11 and 17-19 are withdrawn.

Claim Objections

Claims 3 and 20 are objected to because of the following: In claim 3, "maltohexaose" is mistyped on line 11. In claim 20, "of" is typed instead of "higher than" after "an isoelectric point". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly

Art Unit: 1652

connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 3, with dependent claims 20 and 21, is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Before the amendment of January 14, 2000 claim 3 has been drawn to a DNA encoding an α -amylase having an amino acid sequence of SEQ ID NO:2 with one or more amino acids substituted, added, deleted or inserted. By the amendment of January 14, 2000 claim 3 has been amended to recite the specific substrate specificity of an α -amylase.

"Applicants do not believe that it is new matter to add this characterization of the enzymatic activity of the encoded protein of claim 3 ... , because the activity is an inherent property of the enzyme" (page 7, 2nd paragraph, of Remarks of 1/14/00). The examiner agrees with this statement in relation to the α -amylase having the amino acid sequence of SEQ ID NO:2. In fact, said α -amylase is the only amylase with the requisite properties that has been disclosed in '881 or instant application. Claim 3, as amended, encompasses a great number of α -amylases having unknown structures and possessing the requisite properties. The Examiner is unable to locate adequate support in the specification for such α -amylases . Thus there is no indication that α -amylases

Art Unit: 1652

having amino acid sequences other than SEQ ID NO:2 and having the requisite properties were within the scope of the invention as conceived by Applicants at the time the application was filed.

Accordingly, Applicants are required to cancel the new matter in the response to this Office Action.

The following rejection is the written description rejection.

Claim 3 is drawn to a DNA encoding an α -amylase having an amino acid sequence of SEQ ID NO:2 with one or more amino acids substituted, added, deleted or inserted and having the specific substrate specificity. Claims 20 and 21 recite additional properties. There is no limitation on the structural homology. Therefore, claim 3 is equivalent to a claim wherein no amino acid sequence is recited. Such mutant and a DNA encoding thereof encompass a great number of molecules, both naturally occurring and synthetic, encoding amino acid sequences some of which may not have any structural homology with SEQ ID NO: 2. Claims 20 and 21 recite a nucleic acid sequence encoding an amylase having the requisite substrate specificity and some specific physicochemical properties from any biological source. Applicants disclose one DNA molecule, the DNA encoding alkaline liquefying α -amylase from *Bacillus* sp. KSM-AP1378 having SEQ ID NO:1 and encoding the amino acid sequence of SEQ ID NO:2. Several bacterial α -amylases are known in the art. Claim 3

Art Unit: 1652

encompasses DNAs encoding said enzyme from all possible sources which would include fungi, plants, animals, etc. The specification does not disclose identifying characteristics which would allow to recognize a DNA encoding alkaline liquefying α -amylase of all origins nor they are known in the art. Therefore, based on the instant disclosure, it is unpredictable which DNA will encode an alkaline liquefying α -amylase with the desired properties. Thus, a DNA encoding alkaline liquefying α -amylase with the requisite properties lacks sufficient written description.

Claims 3, 4, 15, 16, 20 and 21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a DNA encoding an α -amylase having an amino acid sequence of SEQ ID NO:2 that has the specific substrate specificity, does not reasonably provide enablement for a DNA encoding an α -amylase having an amino acid sequence of SEQ ID NO:2 with one or more amino acids substituted, added, deleted or inserted and having the requisite properties. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The specification does not enable any person skilled in the art to make and use the invention commensurate in scope with these claims. The claims are broader than the enablement provided by the disclosure with regard to the huge number of all

Art Unit: 1652

possible nucleic acid sequence encoding α -amylase having the specific desired characteristics.

Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The nature and breadth of the claimed invention encompasses any nucleic acid sequence encoding any α -amylase having an amino acid sequence of SEQ ID NO:2 with one or more amino acids substituted, added, deleted or inserted and having the specific characteristics from any biological source, or derived by any type of mutation from SEQ ID NO: 2. This reads on any structure without any structural limitations having an α -amylase activity with the requisite properties. The specification provides guidance and examples for obtaining a DNA having the nucleotide sequence of SEQ ID NO:1 encoding an α -amylase having an amino acid sequence of SEQ ID NO:2 from *Bacillus* sp. KSM-AP1378. While molecular biological techniques and genetic manipulation to make and use the claimed nucleic acid sequences are known in the prior art and the skill of the artisan are well developed, knowledge regarding the amino

Art Unit: 1652

acid residues which are important to the catalytic activity and folding of the α -amylase, the amino acid residues which can be inserted into or deleted from the amino acid sequence of SEQ ID NO: 2 without affecting the specific catalytic activity, amino acid homology among α -amylase with said specific catalytic activity from various biological sources, and the nucleic acid sequence homology among nucleic acid sequences encoding said α -amylase from various biological sources is lacking. Thus, searching for an α -amylase or a mutant with desired characteristics is well outside the realm of routine experimentation and predictability in the art of success is extremely low. The amount of experimentation to identify a nucleic acid sequence encoding α -amylase with the requisite characteristics of unknown structure is enormous. Since routine experimentation in the art does not include screening vast numbers of genomic or cDNA libraries constructed from large number of biological sources where the expectation of obtaining the desired α -amylase is unpredictable, one skilled in the art would require additional guidance, such as information regarding the three dimensional structure of the α -amylase of SEQ ID NO: 2, the amino acid sequences homologies among α -amylase, the biological source of the enzymes and their catalytic properties and the amino acids which can be mutated without an adverse effect on the function of the enzyme. Without such a guidance, the experimentation left to those skilled in the art is undue.

Art Unit: 1652

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2, with dependent claims 5-7 and 14, and claim 3 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 refers SEQ ID NO:1 where it appears SEQ ID NO:2 is intended. Claim 2 recites a "functional fragment having α -amylase activity". "[F]unctional" is redundant.

It is unclear what is the difference between "added" and "inserted" in claim 3.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3, 4, 15 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Tsukamoto et al. or Yuuki et al.

Tsukamoto et al. and Yuuki et al. (form PTO-1449) teach a DNA encoding an alkaline liquefying α -amylase from *Bacillus* sp. #707 and *Bacillus licheniformis*, respectively. They disclose vectors containing said DNAs and cells transformed with

Art Unit: 1652

the same. DNAs disclosed by Tsukamoto et al. and Yuuki et al. encode amino acid sequences which have about 87% and 69% of identical residues with SEQ ID NO:2, respectively. Therefore, they can be construed as DNAs encoding SEQ ID NO:2 having substitutions, deletions and additions.

In their Remarks filed March 10, 2000, Applicants argue that "the amylase of Tsukamoto et al., i.e. 707 amylase, only shares 83.5% homology with the present amylase. In addition, the 707 amylase of Tsukamoto et al. has a pH optimum of 7, molecular weight of 58,000 and an isoelectric point of 6.5. The amylase of Yuuki et al. has 66.5% homology with the amylase of the present invention and ... has a pH optimum of 5-8 and a temperature optimum of 76° C, with a heat-resistance of 60° C" (paragraph bridging pages 7 and 8). These arguments are not persuasive because these biochemical and physicochemical properties are not recited in claim 3.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1652

Claims 3, 4, 15, 16, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ara et al. in view of Tsukamoto et al. or Yuuki et al.

As explained on page 4 above, claim 3 is equivalent to a claim wherein no amino acid sequence is recited. Therefore, claim 3 and claims 20-21 read on a DNA encoding an amylase with the specific properties.

Ara et al. (EP 0670 367 A1, form PTO-1449) teach the enzyme of the instant invention.

The teachings of Tsukamoto et al. and Yuuki et al. Are outlined above.

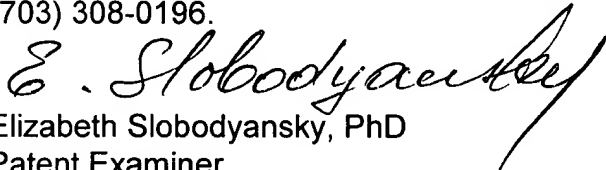
It would have been obvious to one of ordinary skill in the art at the time the invention was made to isolate a DNA encoding an alkaline liquefying α -amylase from *Bacillus* sp. KSM-AP1378 following the procedures taught by Tsukamoto et al. and Yuuki et al. The motivation is provided by Ara et al. who taught the amylase of *Bacillus* sp. KSM-AP1378. One skilled in the art would have a reasonable expectation of success because the amylases of Tsukamoto et al. and Yuuki et al and DNAs encoding thereof have been isolated from *Bacillus* species.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 308-4242.

Art Unit: 1652

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.


Elizabeth Slobodyansky, PhD
Patent Examiner

May 16, 2000